AmeriWater

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OCT - 5 2011

510(K) SUMMARY

510(K) Number:	**K111740**
Submitter:	AmeriWater
Contact:	Brian R. Bowman, Quality & Regulatory Administrator 1303 Stanley Avenue, Dayton, OH 45404 Phone: (937)461-8833 Fax: (937)461-1988 brianbowman@ameriwater.com
Date Prepared:	September 6, 2011
Proprietary Name:	AmeriWater MRO Portable Reverse Osmosis System
Common Name:	Reverse Osmosis System
Classification Name:	Water purification system for hemodialysis
Classification:	Class II Medical Device under §876.5665 Panel: Gastroenterology Product Code: FIP
Equivalent Device:	K924695, AmeriWater (Dayton Water Systems) Aseptech Portable RO+ system K991519, AmeriWater Water Purification System

Device Description: Osmosis is a natural process where two liquids of different concentration are separated by a semi-permeable membrane and the liquid moves from the lower concentration to the higher concentration in order to achieve chemical potential equilibrium. Reverse osmosis, the scientific concept used in the AmeriWater MRO Portable Reverse Osmosis System, is the opposite of osmosis. Liquid is forced from a region of higher solute concentration through a semi-permeable membrane to a region of lower solute concentration. This is achieved by applying a pressure in excess of the osmotic pressure. Osmotic pressure is the pressure which needs to be applied to a solution to prevent the inward flow of water across a semi-permeable membrane. The MRO system uses a submersible pump to apply the pressure required for reverse osmosis.

The semi-permeable membrane used in the MRO system is a thin film composite (TFC) membrane. A TFC membrane is essentially a molecular sieve constructed in the form of a film from two or more layered materials. The membranes are made out of polyamide, chosen for its permeability to water and relative impermeability to various dissolved impurities and unfilterable molecules.

The MRO Portable Reverse Osmosis System purifies tap water by applying pressure (greater than the osmotic pressure difference) to the feed water supply in order to reverse the water flow through the semi-permeable reverse osmosis membrane so that the water moves from a more concentrated solution to a less concentrated solution resulting in purified permeate flow. Basically, the tap water is supplied to the MRO pump where ist is pressurized and sent to the membrane. The membrane splits the tap water into permeate, which has passed through the membrane, and the concentrate, which passes over the membrane and carries the contaminants to

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drain. The AmeriWater MRO Reverse Osmosis System produces water that meets ANSI/AAMI RD62 requirements for water used in hemodialysis applications. It provides quiet operation for bedside use and may be used for acute care cases, small dialysis wings in a hospital, or for home care. Materials that contact the product water include: ABS, Acrylic, Carbon, Nylon, PVC, Polyester, Polyethylene, Polypropylene, Stainless Steel, Tygon, EPDM, Viton, and Buna N.

Tap water enters the AmeriWater MRO Portable Reverse Osmosis System and passes through dual carbon block filters to remove chlorine, chloramines, and sediment which may damage the RO membranes. The dual chloramine removal carbon cartridges are a special blended carbon block design that satisfies AAMI and CMS requirements. Rated at 1 micron, the filters have a capacity of 8000 gallons with 3 PPM of chloramine at 9.5 pH. The submersible RO pump then pressurizes the feed water to pressures greater than the osmotic pressure. The pressurized feed water is sent through the RO membranes where contaminants are removed, and the feed water is split into permeate, or product water, and concentrate, or reject water. The purified permeate water passes through a Nephros Dsu filter capsule (K110285) to remove microbiological contaminants (down to 0.005 microns) and then is directed to the point of use. A portion of the reject water is returned to the RO pump to reduce waste, and the remainder is sent to drain. Optional antiscalant (K991519) may be included for use on un-softened water supplies to remove hardness minerals that may scale the membrane.

The AmeriWater MRO Portable Reverse Osmosis System includes safety features for the benefit of the user and to protect patient safety. The safety features meet current AAMI requirements and include product water conductivity monitor with audible alarm, a low –pressure cut-off switch to prevent damage to the RO pump in low pressure situations, and a divert to drain feature that prevents product water with conductivity above the alarm set point limit from being used for patient treatment. The MRO also includes a simple disinfection procedure using hydrogen peroxide/peroxyacetic acid (PAA).

Indications for Use: The AmeriWater MRO Portable Reverse Osmosis Systems are water treatment systems intended for use in hemodialysis applications. They are designed to pre-treat and purify potable water for use in making dialysate for hemodialysis and to meet current AAMI and Federal (U.S.) standards. The AmeriWater Portable MROS model is intended for use in a hospital, clinic, dialysis center, or for home care for single patient use. The AmeriWater Portable MRO1 model is for treatment of up to two patients in a hospital, clinic, or dialysis centers. When used as a medical device, Federal law restricts this device to sale by or on the order of a physician per 21CFR §801.109 (b)(1).

Statement of Substantial Equivalence: The AmeriWater MRO Portable Reverse Osmosis System is substantially equivalent in intended use, function, and technology to the AmeriWater (Dayton Water Systems) Aseptech Portable RO+ systems currently cleared for market under K924695, and the AmeriWater RO+ systems currently cleared for market under K991519. The new device is basically the same design as the predicate device with the exception of controller modifications to meet the requirements of UL 60601-1. In addition, new features have been added to meet current AAMI requirements. These include dual carbon block filters equivalent to carbon beds with 10-minute empty bed contact time. The carbon block filters replace the single carbon tank previously used in the MRO. A product water divert to drain feature has also been added. This feature diverts all water to drain if the permeate conductivity exceeds the alarm set point limit. The Nephros Dsu filter capsule (K110285) has also been added in order to help meet the new AAMI requirements for microbiological contaminants. The basic flow path and scientific concepts for the device have not changed, nor has the intended use, electrical requirements, or environmental and incoming water specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Brian R. Bowman
Quality & Regulatory Administrator
AmeriWater, Inc.
1303 Stanley Avenue
DAYTON OH 45404

OCT - 5 2011

Re: K111740
Trade/Device Name: AmeriWater MRO Portable Reverse Osmosis System
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: September 6, 2011
Received: September 19, 2011

Dear Mr. Bowman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K111740

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111740